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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,594	11/07/2001	Eric Olson	UTSD:729US/SLH	8497
7590		12/05/2003	EXAMINER	
Steven L. Highlander		BERTOGLIO, VALARIE E		
Fulbright & Jaworski L.L.P.		ART UNIT		
Suite 2400		PAPER NUMBER		
600 Congress Avenue		1632		
Austin, TX 78701		DATE MAILED: 12/05/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/045,594		OLSON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Valarie Bertoglio		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 13-18 and 20-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>04/29/2002</u> | 6) <input checked="" type="checkbox"/> Other: <i>Notice to Comply</i> .     |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group IV, claims 10-12 and 19 in the response received 03/24/2003 is acknowledged. Claims 1-9,13-18 and 20-105 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse. Claims 1-105 are pending and claims 10-12 and 19 are under current examination.

### *Sequence Compliance*

The Computer Readable Format of the Sequence Listing filed 09/02/2003 has been received and entered.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequence in Figures 1A-1D and 2A-2D require sequence identification numbers either on the figure or in the figure description.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified nucleic acid, wherein said nucleic acid encodes a fusion polypeptide comprising SEQ ID NO:2 and a subcellular localization signal wherein the subcellular localization signal localizes said fusion polypeptide to a subcellular region other than the subcellular region of normal function for calcineurin, does not reasonably provide enablement for an isolated and purified nucleic acid, wherein said nucleic acid encodes a fusion polypeptide comprising SEQ ID NO:2 and fused to any polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use, the invention commensurate in scope with these claims.

Claim 19 is drawn to a nucleic acid encoding a fusion protein comprising SEQ ID NO:2. The breadth of the claim encompasses any fusion polypeptide including a fusion to a marker such as GFP, a secretory signal, a subcellular localization signal, a degradation signal, another functional polypeptide, or an antigenic polypeptide such as HA, among other things.

The specification does not enable using an isolated and purified nucleic acid encoding a fusion polypeptide comprising SEQ ID NO: 2. The specification teaches a fusion protein comprising calsarcin (SEQ ID NO:2) and a subcellular localization signal that targets calsarcin to a subcellular region other than a subcellular region of endogenous function (page 10, lines 15-20; page 20, line 23-page 21, line 2). The specification teaches using said abnormally localized

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calsarcin to bind calcineurin, localizing to a subcellular region other than that of normal calcineurin function, inhibiting calcineurin activation of gene transcription. The specification does not teach a use for other types of fusion polypeptides such as those comprising SEQ ID NO:2 and a polypeptide with enzymatic activity or a degradation signal. The art fails to teach any calsarcin fusion polypeptides. The specification and the art at the time of filing does not teach how to use a fusion protein comprising SEQ ID NO:2 and signal sequences other than those which cause aberrant localization, including secretory signals, degradation signals, marker proteins or peptides with enzymatic activity. Thus, one of skill in the art would not know how to use a nucleic acid encoding a fusion polypeptide comprising SEQ ID NO:2 wherein SEQ ID NO:2 is fused to any nucleic acid sequence. It would require undue experimentation for one of skill in the art to determine how to use the broad genera of fusion polypeptides encompassed by the claim.

***Claim Rejections - 35 USC § 112-2nd paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “segment” in claims 10-12 and 19 is unclear. It is not clear what the term is referring to. The term implies that the nucleic acid is not complete. The term is interpreted as meaning “molecule” which is remedial. Deletion of the term “segment” would make the claims read more clearly.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1) Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Ievolella (06/06/2000; Genbank Accession No. AJ252149).

Claims are drawn to an isolated and purified nucleic acid comprising a nucleic acid encoding SEQ ID NO:2.

Ievolella taught a nucleic acid encoding the polypeptide set forth by SEQ ID NO:2.

Therefore, Ievolella meets the limitations of the claim.

2) Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Ahmad (04/12/2000; Genbank Accession No. AF249873).

Claims are drawn to an isolated and purified nucleic acid comprising a nucleic acid encoding SEQ ID NO:2.

Ahmad taught a nucleic acid encoding the polypeptide set forth by SEQ ID NO:2.

Therefore, Ahmad meets the limitations of the claim.

3) Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Tang (EFD, 01/21/2000; USSN 10/098841; US20020197679A1, SEQ ID NO: 286, alignment enclosed).

Claims are drawn to an isolated and purified nucleic acid comprising a nucleic acid encoding SEQ ID NO:2.

USSN 10/098841 taught a nucleic acid encoding the polypeptide set forth by SEQ ID NO:2.

Therefore, USSN 10/098841 meets the limitations of the claim.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Note: After January 13, 2004, the Examiner may be reached at (571) 272-0725, and should the Examiner be unavailable, inquiries may be directed to Deborah Reynolds, SPE of Art Unit 1632 at (571) 272-0734.

Valarie Bertoglio  
Examiner  
Art Unit 1632



**MICHAEL WILSON**  
**PRIMARY EXAMINER**